

REMARKS

I. Rejection under 35 USC §102

Claims 1,3, 6-10, 12 and 15-18 have been rejected under 35 USC §102(b) as being anticipated by Richardson et al. (US 5,490,980). The office action states in pertinent part that :

Richardson discloses a method of cross-linking human keratin proteins, including those found in hair, by applying a composition comprising an effective amount of transglutaminase to hair. Richardson also discloses a method of covalently bonding an alkyl amine moiety, such as in lysine, to a glutamine residue, both of which are contained in the keratin of hair, by contacting the hair with a composition comprising an effective amount of a transglutaminase...The source of the transglutaminase may be mammalian or microbial and may be present in an amount of 0.001 to 20%. Hair inherently possesses a certain degree of curl. Therefore, the application of transglutaminase to hair, described by Richardson, inherently results in retention, enhancing and imparting of curl to hair.

Applicants respectfully disagree with the Examiner's interpretation of the teaching of Richardson, and the interpretation of what is accomplished therein. While it is correct that Richardson does disclose the linking of transglutaminase to glutamine residues on the skin, hair or nails, there are two components to the Richardson reaction on these keratinous surfaces, and it is solely this component that resembles the process of the present invention. In particular, Richardson's intent, and presumed achievement, is to bind an active component to the transglutaminase before applying the transglutaminase to the skin, hair or nails. Therefore, the ultimate crosslinking that occurs on the skin, hair or nails is between the active bound to the transglutaminase and the glutamine residue. Because the glutamine residues will be occupied by the transglutaminase-bound active, they will not be available to be crosslinked to lysine residues on the skin, hair or nails, nor will the transglutaminase, already bound on one site to the active, have the capability of crosslinking the glutamine residues to lysine residues. In other words, because of the binding of active to the transglutaminase before it is applied to the skin, hair or nails, the reaction upon application can go only one way, and that is between the active and glutamine residues, not between glutamine and lysine residues on the skin, hair or nails. In essence, the occupation of a portion of the transglutaminase by an active when it is applied to the target surface renders it a physical impossibility for a crosslinking of lysine and glutamine residues, and therefore crosslinking of *in situ* proteins, on that surface. Thus, there is no possibility of imparting curl or curl retention in following the method of Richardson.

In order to establish an anticipation by inherency, it must be shown that the subject matter being claimed must undeniably and irrefutably flow from the prior art disclosure. *Hughes Aircraft Co.*

v. United States, 8 USPQ 2d 1580 (Ct. Cl. 1988). As shown by the discussion above, not only does the claimed result not undeniably and irrefutably flow from the Richardson disclosure, it unequivocally could not flow from that disclosure. Therefore, the rejection of claims 1, 3, 6-10, 12 and 15-18 under 102(b) must be withdrawn.

II. Rejection under 35 USC §103(a)

A. Claims 1-4, 6-13 and 15-18 have been rejected under 35 USC §103(a) as being unpatentable over Richardson (cited above) in view of Dane, Hair Chemistry, and the record for transglutaminase from BRENDA. The rejection states:

As discussed above, Richardson discloses a method of cross-linking human keratin proteins, including those found in hair, by applying a composition comprising an effective amount of transglutaminase to hair. Richardson also discloses a method of covalently bonding an alkyl amine moiety, such as lysine, to a glutamine residue, both of which are contained in the keratin of hair, by contacting the hair with a composition comprising an effective amount of transglutaminase....Richardson does not disclose the pH of the composition or applying heat to hair after applying the transglutaminase composition. Dana discloses...that in creating curls and waves, disulfide bonds are broken and new ones formed, thereby cross-linking the keratin arrangement. Thus, one of ordinary skill in the art at the time the invention was made would have recognized that in designing a product to maintain or enhance the curl of permed hair, it would have been advantageous to include an ingredient that can cross-link keratin...The skilled artisan would have been motivated to use the method of Richardson to maintain or enhance the curl of permed hair, because Richardson teaches that applying a transglutaminase can not only cross-link hair, it can also condition and repair damaged hair by catalyzing the reaction of primary amines with superficial glutamines in hair keratin...

Regarding the pH of the transglutaminase composition, it is well known in the art that human transglutaminase has a pH optimum of 6...Thus, it would have been obvious to one of ordinary skill in the art that, in preparing a composition comprising transglutaminase, as disclosed by Richardson, an appropriate pH would have been approximately 6.

With respect to applying heat to a keratinous material after applying a transglutaminase-containing composition, it is well known in the pertinent art that, after conditioning or applying a therapeutic treatment composition to hair, the hair may be subjected to heat with a hair dryer or blow dryer to style or reinforce curls. Thus, it would have been obvious to one of ordinary skill in the art that, following treatment of hair with a composition comprising an effective amount of transglutaminase to maintain or enhance curl, as disclosed by Richardson, the hair would have been subjected to heat to style the curled hair or to reinforce the curl. Thus, a holding of obviousness is required.

The rejection as stated above is flawed and cannot be sustained. The principle basis for the flaw is in the analysis of the Richardson reference, already rebutted in detail above. As a brief recap, however, and in specific response to comments made in support of this rejection,

Richardson does not teach that "applying a transglutaminase can not only cross-link hair, it can also condition and repair damaged hair by catalyzing the reaction of primary amines with superficial glutamines in hair keratin". Richardson teaches that transglutaminase can crosslink a residue on hair to an active (see the explicit language of Richardson's claims). It does not teach that it can form crosslinks between hair residues, i.e., completely within hair strands, nor does it even remotely suggest that it would be desirable to use a transglutaminase-containing composition for that purpose. In fact, doing so would completely defeat the purpose of Richardson, because the residues to which the transglutaminase is desired to bind would be tied up with other hair residues, and therefore unavailable for binding with the actives that are the actual material intended to be bound.

It is further clearly incorrect that the Richardson reference teaches that treatment of hair with transglutaminase can condition and repair damaged hair. If the portion of the disclosure cited by the Examiner in support of this position is read carefully, it will be immediately seen that it states that conditioning is achieved by linking primary amines that constitute part of a functional group on an externally applied source, such as alkyl chain/silicone. In fact, the authors go on to disclose specific suitable sources of these amine groups, such as Dow Corning silicone Q2-8220™. It is apparent, upon reading the relevant paragraph in its entirety, that Richardson suggests only that transglutaminase can be used to link an exogenous, amine-containing conditioning agent to the hair; it unquestionably does not disclose that transglutaminase itself is useful in conditioning hair.

Since the primary reference relied on by the Examiner does not, as shown above, contain the teaching that forms the basis of the rejection, the entire rejection cannot be sustained. Without the relevant teaching in Richardson, there is no motivation to combine the Dane disclosure with Richardson, because the stated motivation for the combination is in the teaching in both references of crosslinking (or curling) of hair fibers. Since it has been shown that such a teaching is not found in Richardson, either expressly or inherently, the foundation of the combination, and thus that portion of the rejection fails completely. Even if one did combine the teachings of Dane with Richardson, one would not be provided with any suggestion or direct teaching that transglutaminase could have any effect on curl in hair, because Dane is devoid of

any teaching whatsoever regarding any use of transglutaminase. As to the BRENDA citation¹, it provides no more disclosure of the curl-inducing or -retaining properties than does either Dane or Richardson; therefore, even if the disclosures of all three documents are combined, there is no disclosure to be found anywhere in the combined teachings of the ability of transglutaminase to set up crosslinks within keratin fibers, and thus to curl hair. Establishment of a *prima facie* case of obviousness requires, *inter alia*, that prior art reference(s) teach or suggest all claim limitations. *In re Royka*, 180 USPQ 580 (CCPA 1974; emphasis added). In the absence, in any of the cited documents, of that crucial teaching that the Examiner has relied as the basis for the rejection, the rejection of the claims under 35 USC §103(a) cannot be sustained, and should be withdrawn.

B. Claims 1-18 have been rejected under 35 USC §103(a) as being unpatentable over Richardson et al., in view of Dane, cited above, and further in view of product literature for eyelash perms from E-Z Permanent Makeup. In particular, the office action asserts as follows:

...Richardson discloses a method of cross-linking human keratin proteins and a method of covalently bonding an alkyl amine moiety, such as lysine, to a glutamine residue, both of which are contained in the keratin of hair, by applying a composition comprising an effective amount of transglutaminase to hair...Richardson does not disclose applying a transglutaminase composition to eyelashes. Dane discloses in creating curls, disulfide bonds between the amino acids of keratin in hair are broken and new ones formed, thereby cross-linking the keratin in a new arrangement...E-Z Permanent Makeup discloses that a permanent wave may also be applied to eyelashes, another form of human keratin protein. Accordingly, one of ordinary skill in the art at the time that the invention was made would have recognized that in designing a product to maintain or enhance the curl of permed eyelashes, it would have been advantageous to have included an ingredient that can cross-link keratin, as disclosed by Richardson, to maintain the new cross-linking pattern in the eyelashes resulting from the perm by applying a second cross-linking agent....

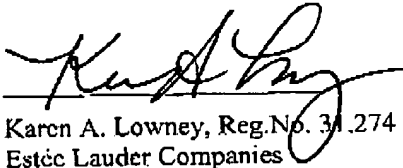
¹ Applicants note that the Examiner has not provided any date for the BRENDA reference, other than the date it was printed from the Internet. That date is not prior to the filing date of the present application, and therefore, there is no evidence that this reference is valid prior art. While it is believed that the reference does not contribute anything to the rejection in which it is applied, Applicants reserve the right to challenge its applicability as prior art if the rejection is maintained

This rejection suffers from the same fatal flaw as the previous rejections do, namely, the failure of the premise that Richardson teaches that transglutaminase can crosslink keratin fibers. The issues, and arguments in rebuttal, are essentially the same as those presented above with regard to the previous rejection, and are incorporated herein by reference. Briefly, as clearly shown above, the Richardson reference does not teach that transglutaminase can cross-link keratin fibers, it only teaches that transglutaminase can be used to cross-link an active to a keratin fiber; no crosslinking within or between fibers is disclosed, nor would it be possible, or even desirable, given the construct of the Richardson composition and purpose of the Richardson method. Without the relevant teaching in Richardson, there is no motivation to even combine either of the Dane or the E-Z Permanent Makeup disclosures with Richardson, because the stated motivation for the combination is in the teaching in all the references of crosslinking (curling) of hair fibers. However, it has been shown Richardson fails to provide this teaching, either expressly or inherently, and therefore the rejection is without any technical or legal basis. In fact, even if the teachings of Dane and E-Z Permanent Makeup are directly combined with Richardson's teachings, one of skill in the art would still not be led to the suggestion that he/she could or would want to use transglutaminase to impart or retain curl in hair, as such a teaching is utterly absent from the combined disclosures of all three references. In view of the absence of the critical teaching, it is no more obvious to apply transglutaminase to curl or retain curl in eyelashes in view of the cited references, than it is to apply it for that purpose to any other keratin fiber. For the reasons stated above, the rejection of claims 1-18 cannot be supported and should be withdrawn.

CONCLUSION

The present claims are believed to be in condition for allowance, and prompt issuance of a Notice of Allowance is respectfully solicited. The Examiner is encouraged to contact the undersigned by telephone if it is believed that discussion will resolve any outstanding issues.

Respectfully submitted,



Karen A. Lowney, Reg.No. 31,274
Estée Lauder Companies
155 Pinelawn Road
Suite 345 South
Melville, NY 11747
(631)414-6086